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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,927	05/30/2001	Robert H. Getzenberg	076333-0240	6351

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Stephen A. Bent
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,927	GETZENBERG, ROBERT H.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 11, and 12, in part, and claims 2 and 8 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-1, classified in class 530, subclass 388.8. If Group I is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-1.

II. Claims 1, 11, and 12, in part and claim 3 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-2, classified in class 530, subclass 388.8. If Group II is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-2.

III. Claims 1, 11, and 12, in part, and claim 4 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-3, classified in class 530, subclass 388.8. If Group III is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-3.

IV. Claims 1, 11, and 12, in part, and claims 5, 9, and 13-15 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-4, classified in class 530, subclass 388.8. NOTE it

is interpreted that claim 9 is dependent on claim 5 not claim 3 as indicated in view of the apparent sequence identifier discrepancies. If Group IV is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-4.

V. Claims 1, 11, and 12, in part, and claim 6 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-5, classified in class 530, subclass 388.8. If Group V is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-5.

VI. Claims 1, 11 and 12, in part, and claims 7 and 10 drawn to an antibody that specifically binds to a nuclear matrix protein or an antigen thereof where as the nuclear matrix protein is BLCA-6, classified in class 530, subclass 388.8. NOTE it is interpreted that claim 10 is dependent on claim 7 not claim 4 as indicated in view of the apparent sequence identifier discrepancy. If Group VI is elected, claims 1, 11, and 12 will be examined to the extent that they read on antibodies that specifically bind BLCA-6.

VII. Claims 16 and 17, in part, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer, comprising contacting a sample with the antibody to BLCA-1, classified in class 435, subclass 7.1. If group VII is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-1.

VIII. Claims 16 and 17, in part, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer, comprising contacting a sample with the antibody to BLCA-2, classified in class 435, subclass 7.1. If group VIII is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-2.

IV. Claims 16 and 17, in part, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer, comprising contacting a sample with the antibody to BLCA-3, classified in class 435, subclass 7.1. If group IV is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-3.

X. Claims 16, 17, in part, and 18, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer, comprising contacting a sample with the antibody to BLCA-4, classified in class 435, subclass 7.1. If group X is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-4.

XI. Claims 16 and 17, in part, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer, comprising contacting a sample with the antibody to BLCA-5, classified in class 435, subclass 7.1. If group XI is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-5.

XII. Claims 16 and 17, in part, drawn to a method of diagnosing a subject having bladder cancer or determining if a subject is at risk of developing bladder cancer,

comprising contacting a sample with the antibody to BLCA-6, classified in class 435, subclass 7.1. If group XII is elected, claims 16 and 17 will be examined to the extent that they read on a method using an antibody to BLCA-6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibodies of groups I-VI are produced by immunization of antigens with distinct characteristics and properties. The antibody of group I is directed toward an antigen BLCA-1 with a molecular weight of about 72 kD and a pI of 7.70; The antibody of group II is directed toward an antigen BLCA-2 with a molecular weight of about 40 kD and a pI of 7.50; The antibody of group III is directed toward an antigen BLCA-3 with a molecular weight of about 39 kD and a pI of 6.27; The antibody of group IV is directed toward an antigen BLCA-4 with a molecular weight of about 37 kD and a pI of 6.24; The antibody of group V is directed toward an antigen BLCA-5 with a molecular weight of about 29 kD and a pI of 5.80; and the antibody of group VI is directed toward an antigen BLCA-6 with a molecular weight of about 22 kD and a pI of 8.00.

Antibodies bind to small structural parts of polypeptides called epitopes. Epitopes may be as small as 4 linear amino acid residues or may be formed by discontinuous sequences. In view of the structural differences of BLCA-1, -2, -3, -4,- 5, and - 6 proteins, as evidenced by the various apparent molecular weight and isoelectric

points, and as evidenced by differing amino acid primary sequences, one skilled in the art would reasonably conclude that antibodies to the BLCA-1, -2, -3, -4,- 5, and - 6 proteins bind to different epitopes.

Absent of evidence showing conserved structural domains, one skilled in the art would not reasonably expect an antibody specific to BLCA-1 to bind to any of the other BLCA-2, -3, -4, -5, or -6 proteins. Further it is expected that the various BLCA-1, -2, -3, -4,- 5, and - 6 antigens would have corresponding differences in cellular locations, hydrophobicity, and protein stability. Accordingly, the making and using antibodies specific for each of the various BLCA-1, -2, -3, -4,- 5, and - 6 proteins would require consideration of different issues such as antigenicity, immunogenicity, cross-reactivity, and accessibility of the epitope, for example.

Therefore, the examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-VI are patentably distinct.

The methods of Inventions VII-XII differ in the reagents used. Invention VII recites a method of diagnosis using an antibody toward BLCA-1; Invention VIII recites a method of diagnosis using an antibody toward BLCA-2; Invention IX recites a method of diagnosis using an antibody toward BLCA-3; Invention X recites a method of diagnosis using an antibody toward BLCA-4; Invention XI recites a method of diagnosis using an antibody toward BLCA-5; and Invention XII recites a method of diagnosis using an antibody toward BLCA-6;

As set forth above, each of the various BLCA-1, -2, -3, -4,- 5, and - 6 antigens present different structural features which would raise different issues in antigenicity, immunogenicity, cross-reactivity, and accessibility, for example. Absent of evidence of a common structural domain between each of the BLCA-1, -2, -3, -4,- 5, and - 6 antigens, one skilled in the art would reasonably conclude that an antibody specific to BLCA-1, for example, would not bind any of the other BLCA-2, -3, -4, -5, or -6 antigens.

Therefore, the examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions VII-XII are separate and distinct in having different method reagents and are patentably distinct.

Inventions (I-VI) and (VII-XII) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Inventions I-VI can be used in a materially different process such as immunopurificatation as well as the method of diagnosis as recited for inventions VII-XII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different classifications, restriction for examination purposes as indicated is proper.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879